



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11) **EP 1 166 744 A1**

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:  
02.01.2002 Bulletin 2002/01

(51) Int Cl.7: **A61K 6/00**

(21) Application number: 01113009.3

(22) Date of filing: 28.05.2001

(84) Designated Contracting States:  
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU  
MC NL PT SE TR**  
Designated Extension States:  
**AL LT LV MK RO SI**

(72) Inventors:  
• Muramatsu, Hiroaki  
Konosu-shi, Saitama-ken (JP)  
• Sekiguchi, Toshihiro  
Hatogaya-shi, Saitama-ken (JP)

(30) Priority: 19.06.2000 JP 2000182862

(74) Representative: Becker Kurig Straus  
Patentanwälte Bavariastrasse 7  
80336 München (DE)

(71) Applicant: Healthtech Corporation  
Tokyo (JP)

(54) **Denture adhesive**

(57) There is provided an adhesion type denture adhesive having superior cleanability, which can be easily removed from a denture base and an oral mucosa for cleansing after the use, while possessing a superior

force for stabilizing a denture. The denture adhesive containing a water-soluble polymer as a main ingredient, and containing 0.5 to 60 % by weight of an alginate and 0.1 to 20 % by weight of calcium sulfate contained therein.

EP 1 166 744 A1

## Description

**BACKGROUND OF THE INVENTION****1. Field of the Invention:**

[0001] The present invention relates to an adhesion type denture adhesive having superior cleanability, which can be easily removed from an oral mucosa and a denture base for cleansing after the use.

**2. Description of the Conventional Art:**

[0002] A denture adhesive is a material for making unfitted denture stable in a mouth and exhibits an effect for compensating occlusion or mastication to make a person easy to talk. Such a denture adhesive is classified in terms of composition into a so-called "close contact type" denture adhesive containing a vinyl acetate resin as a main ingredient and "an adhesion type" denture adhesive containing a water-soluble polymer having high adhesiveness, such as karaya gum and sodium carboxymethyl cellulose, as a main ingredient.

[0003] The close contact type denture adhesive is a denture adhesive that removes air between a denture base and an oral mucosa and vacuum adsorbs a denture on the mucosa surface, thereby stabilizing the denture due to its adhesive properties. In general, the close contact type denture adhesive is an elastic rubber-like paste containing a vinyl acetate resin as a main ingredient. Since this close contact type denture adhesive is insoluble in water, it has characteristics that it is possible to take out the denture from the mouth and wash it with water and that it can be used even in the case where a gap between the denture base and the oral mucosa is relatively large. Further, it can be easily separated from the oral mucosa. However, the close contact type denture adhesive has involved defects such that it has irritation on the oral mucosa due to an alcohol present as one ingredient therein and that the denture adhesive is liable to remain on the resin-made denture surface, whereby works for removing the denture adhesive from the denture base for cleansing after the use are very difficult.

[0004] On the other hand, the adhesion type denture adhesive is a denture adhesive containing a water-soluble polymer such as karaya gum and sodium carboxymethyl cellulose, as a main ingredient, in which the water-soluble polymer comes into contact with a saliva between the denture base and the oral mucosa and is swollen and dissolved therein, thereby exhibiting adhesiveness and making the denture stick to the oral mucosa for stabilization.

[0005] The adhesion type denture adhesive is further classified, depending on the shape, into a powdered form; a paste-like form prepared by mixing the water-soluble polymer powder with a mineral oil such as Vaseline and liquid paraffin, or an anhydrous polyhydric alcohol such as glycerin and polyethylene glycol; and a sheet-like form prepared by once dissolving the water-soluble polymer powder in a solvent and then drying it by lyophilization or the like.

[0006] The adhesion type denture adhesive in any form is superior in stabilization effect to the close contact type denture adhesive and has a characteristic such that it is less in a feeling of wrongness because it can be applied uniformly and thinly between the oral mucosa and the denture base. However, the adhesion type denture adhesive has involved defects such that, since the water-soluble polymer that has been swollen and dissolved in moisture is in a paste-like state, works for removing the denture adhesive stuck to the denture base or oral mucosa for cleansing after the use are difficult and that the denture adhesive attached on the denture base or mucosa surface cannot be easily removed.

**SUMMARY OF THE PRESENT INVENTION**

[0007] An object of the present invention is to overcome the above-described defects of the denture adhesive of the conventional art and provide an adhesion type denture adhesive having superior cleanability while keeping a superior denture stabilization effect, which can be easily removed from a denture base and an oral mucosa for cleansing after the use.

[0008] We, the present inventors made extensive and intensive investigations in order to achieve the above-described object. As a result, it has been found that when suitable amounts of an alginate and calcium sulfate are mixed into an adhesion type denture adhesive containing a water-soluble polymer as a main ingredient, not only the resulting adhesion type denture adhesive has superior adhesiveness due to swelling and dissolution of the water-soluble polymer upon contact with moisture such a saliva, but also it becomes in a gel-like state due to a fact that a calcium alginate gel formed by the reaction of the alginate and calcium sulfate during the contact with moisture contains a paste of the water-soluble polymer, whereby it can be easily removed, together with the water-soluble polymer, from a denture base or an oral mucosa for cleansing after the use, leading to accomplishment of the invention.

[0009] Specifically, the denture adhesive according to the invention is a denture adhesive containing a water-soluble polymer as a main ingredient, and containing 0.5 to 60 % by weight of an alginate and 0.1 to 20 % by weight of calcium

sulfate.

## DETAILED DESCRIPTION OF THE PRESENT INVENTION

[0010] As the denture adhesive according to the present invention, any conventional denture adhesive that has hitherto been used can be used without particular restrictions so far as it contains a water-soluble polymer as a main ingredient and utilizes adhesiveness by swelling and dissolution of the water-soluble polymer. When suitable amounts of an alginate and calcium sulfate are mixed into this adhesion type denture adhesive, the resulting denture adhesive can be easily removed from a denture base and an oral mucosa for cleansing after the use, and consequently, it possesses superior cleanability.

[0011] Examples of the water-soluble polymer that has hitherto been used for the present invention include kayara gum, sodium carboxymethyl cellulose, gum arabic, sodium polyacrylate, and a methoxy ethylene-maleic anhydride copolymer. In the invention, two or more of these water-soluble polymers can also be used at the same time.

[0012] Examples of the alginate that is used for the denture adhesive according to the present invention include sodium alginate, potassium alginate, ammonium alginate, and magnesium alginate. A suitable amount of the alginate to be mixed is 0.5 to 60 % by weight, and preferably 5 to 30 % by weight. When the amount of the alginate to be mixed is less than 0.5 % by weight, the effect by a calcium alginate gel cannot be provided. On the other hand, when it exceeds 60 % by weight, the operability during the use of the denture adhesive is deteriorated.

[0013] The higher a molecular weight of the alginate, the higher a gel strength of calcium alginate as formed, and hence, such is more suitable. Since it is difficult to define the molecular weight of the alginate, it is general to define the molecular weight in terms of a viscosity under prescribed conditions. Accordingly, it is preferred that the alginate used in the invention has a viscosity of 50 to 1,000 cP, and preferably 700 to 1,000 cP at 25 °C in terms of 1 % by weight aqueous solution.

[0014] Calcium sulfate that is used for the denture adhesive according to the invention may be in the form of either a dihydrate or a semi-hydrate. A suitable amount of calcium sulfate to be mixed is 0.1 to 20 % by weight, and preferably 0.3 to 8 % by weight. When the amount of calcium sulfate to be mixed is less than 0.1 % by weight, the effect for gelling the alginate is not provided. On the other hand, when it exceeds 20 % by weight, the fluidity of the denture adhesive during the use is deteriorated, so that the denture adhesive cannot be thinly applied in a gap between the denture base and the oral mucosa.

[0015] The denture adhesive according to the invention may be in any of a powder form, a paste-like form, or a sheet-like form, like the adhesion type denture adhesive of the conventional art. In the case where the denture adhesive according to the present invention is in a powder form, a water-soluble polymer powder, an alginate powder and a calcium sulfate powder are mixed and then provided. In this case, the denture adhesive powder is sprayed on a denture base that is moistened by water in advance, and an excess of the denture adhesive is shaken off, followed by inserting the denture into a mouth and providing it for the use.

[0016] In the case where the denture adhesive according to the present invention is in a paste-like form, the mixture in a powder form is mixed with a mineral oil such as Vaseline and liquid paraffin, or an anhydrous polyhydric alcohol such as glycerin and polyethylene glycol, in an amount of at most 60 % by weight, and preferably 15 to 60 % by weight, to prepare a paste. In comparison with the powdered denture adhesive, the paste-like denture adhesive does not require a denture to be moistened with water in advance and is spread more uniformly and thinly on the denture base surface. Thus, the latter is superior in the operability.

[0017] In the case where the denture adhesive according to the invention is in a sheet-like form, the respective components including the water-soluble polymer, the alginate and the calcium sulfate are once mixed in a solvent and then dried by lyophilization or the like, to prepare a sheet. The sheet-like denture adhesive is moistened by water and laminated on the denture base surface to adjust the shape, followed by inserting the denture into a mouth and providing it for the use.

[0018] As a matter of course, the denture adhesive according to the present invention can be mixed with other optional components so far as the effects of the invention are not inhibited. Examples of such optional components that can be used in the present invention include a preservative, a pH adjustor, an enzyme, a pigment, and a fragrance or flavor.

[0019] The invention will be specifically described with reference to the following Examples, but it should not be construed that the invention is limited thereto. In each of the Examples and Comparative Examples, the alginate was designated with a viscosity at 25 °C in terms of a 1 % by weight aqueous solution.

## EP 1 166 744 A1

Example 1:

[0020]

Karaya gum	30 % by weight
Sodium alginate (780 cP)	15 % by weight
Calcium sulfate (dihydrate)	5 % by weight
Liquid paraffin	50 % by weight

[0021] The above components were mixed to obtain a paste-like denture adhesive.

Example 2:

[0022]

Sodium carboxymethyl cellulose	40 % by weight
Potassium alginate (800 cP)	10 % by weight
Calcium sulfate (dihydrate)	3 % by weight
White Vaseline	47 % by weight

[0023] The above components were mixed to obtain a paste-like denture adhesive.

Example 3:

[0024]

Sodium polyacrylate	41 % by weight
Sodium alginate (700 cP)	4 % by weight
Calcium sulfate (dihydrate)	2 % by weight
Glycerin	53 % by weight

[0025] The above components were mixed to obtain a paste-like denture adhesive.

Example 4:

[0026]

Karaya gum	20 % by weight
Potassium alginate (580 cP)	25 % by weight
Calcium sulfate (semi-hydrate)	15 % by weight
Polyethylene glycol	40 % by weight

[0027] The above components were mixed to obtain a paste-like denture adhesive.

Example 5:

[0028]

Sodium polyacrylate	70 % by weight
Sodium alginate (800 cP)	25 % by weight
Calcium sulfate (semi-hydrate)	5 % by weight

[0029] The above components were mixed to obtain a powdered denture adhesive.

Example 6:

[0030]

Sodium polyacrylate	60 % by weight
Magnesium alginate (580 cP)	30 % by weight
Calcium sulfate (dihydrate)	10 % by weight

[0031] The above components were mixed to obtain a powdered denture adhesive.

Comparative Example 1:

[0032]

Karaya gum	35 % by weight
Calcium sulfate (dihydrate)	15 % by weight
Polyethylene glycol	50 % by weight

[0033] The above components were mixed to obtain a paste-like denture adhesive.

Comparative Example 2:

[0034]

Karaya gum	35 % by weight
Potassium alginate (780 cP)	25 % by weight
Polyethylene glycol	40 % by weight

[0035] The above components were mixed to obtain a paste-like denture adhesive.

[0036] Each of the above-described compositions was evaluated with respect to the cleanability and adhesion in the following manners. The results obtained are shown in Table 1.

Measurement of adhesion:

[0037] On an acrylic resin plate of  $\phi 10$  mm x 3 mm, were placed 0.2 g of each of the denture adhesives of the Examples and Comparative Examples and 0.1 g of water. Another acrylic resin plate having the same size was put on the denture adhesive so that the denture adhesive was sandwiched by the two acrylic resin plates. After applying a load of 1 kg for 10 seconds, the denture adhesive as forced out was removed out, and the resulting assembly was allowed to stand at a temperature of 37 °C and at a humidity of 100 % for 10 minutes. Then, a force necessary for peeling apart the acrylic resin plates was measured.

Cleanability:

[0038] Each of the denture adhesives of the Examples and Comparative Examples was applied on a denture base and inserted into a mouth in a customary manner. Five hours after the insertion, the denture base was taken out from the mouth, and easiness of the removal of each of the denture adhesives from the denture base and mouth was evaluated. The cleansing method and evaluation method were carried out in the following manner. That is, the denture base side was cleansed lightly with running water by a brush for denture cleansing, and the time until the denture adhesive had been removed from the denture base surface was evaluated. In the oral mucosa side, the inside of the mouth was rinsed with water for one minute, and the amount of the denture adhesive remaining on the oral mucosa surface was visually evaluated according to the following criteria.

- A: The denture adhesive did not substantially remain.  
B: A slight amount of the denture adhesive remains.  
C: A considerable amount of the denture adhesive remains attached onto the mucosa surface.

Table 1

	Adhesion (kgf)	Cleanability	
		Denture base	Oral mucosa
Example 1	0.65	20 sec.	A
Example 2	0.62	15 sec.	A
Example 3	0.65	15 sec.	A
Example 4	0.63	20 sec.	A
Example 5	0.60	15 sec.	A
Example 6	0.59	15 sec.	A
Comparative Example 1	0.50	1 min.	B
Comparative Example 2	0.52	1 min.	C

[0039] As is clear from the results shown in Table 1, it can be confirmed that the denture adhesive according to the present invention is a denture adhesive that can be easily cleansed after the use, while possessing superior adhesion equal to or more than that of the adhesion type denture adhesives of the conventional art.

[0040] In the light of the above, the denture adhesive according to the invention is a denture adhesive prepared by mixing suitable amounts of an alginate and calcium sulfate into an adhesion type denture adhesive containing a water-soluble polymer as a main ingredient, which has a sure force for stabilizing a denture by utilizing superior adhesive properties due to the water-soluble polymer and adhesiveness due to an effect of a calcium alginate gel formed by the reaction of the alginate and calcium sulfate, and has superior cleanability due to an effect of the calcium alginate gel formed by the reaction of the alginate and calcium sulfate. Accordingly, the denture adhesive according to the invention is greatly valuable in contributing to users of a denture, the number of which is recently increasing according to the aging.

[0041] While the invention has been described in detail and with reference to specific embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made therein without departing from the spirit and scope thereof.

#### Claims

1. A denture adhesive containing a water-soluble polymer as a main ingredient, and containing 0.5 to 60 % by weight of an alginate and 0.1 to 20 % by weight of calcium sulfate.



European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number  
EP 01 11 3009

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	US 4 608 088 A (LOKKEN ODDVIN) 26 August 1986 (1986-08-26) * column 4, line 30 - column 4, line 55; claims *	1	A61K6/00
X	US 4 339 279 A (HESSELGREN SVEN-GUNNAR) 13 July 1982 (1982-07-13) * column 5, line 1 - column 5, line 52 *	1	
X	US 4 468 484 A (PELLICO MICHAEL A) 28 August 1984 (1984-08-28) * column 4, line 30 - column 4, line 55; claims *	1	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61K
The present search report has been drawn up for all claims			
Place of search MUNICH		Date of completion of the search 8 October 2001	Examiner Fouquet, M
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons &amp; : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03 82 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 01 11 3009

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

08-10-2001

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4608088	A	26-08-1986	US	4664630 A	12-05-1987
US 4339279	A	13-07-1982	SE	424955 B	23-08-1982
			DE	2924095 A1	20-12-1979
			GB	2028852 A ,B	12-03-1980
			SE	7806939 A	17-12-1979
			US	4406708 A	27-09-1983
US 4468484	A	28-08-1984	US	4381947 A	03-05-1983
			AU	553718 A1	24-07-1986
			EP	0126824 A2	05-12-1984
			EP	0198131 A1	22-10-1986
			JP	59204113 A	19-11-1984
			US	4515913 A	07-05-1985

EPO FORM P4419

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82